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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Reference Docket No. 96N-0393

Dear Sir/Madam:

Amgen appreciates the opportunity to provide comments on "MedWatch: The FDA Medical Products Reporting Program" forms (Form FDA 3500 (voluntary version) and Form FDA 3500A (mandatory version)). With respect to the collection of information, our comments are formatted in accordance with the questions posed in the July 26, 2000 Federal Register Notice.

- (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.
 - Of the 273,109 Form 3500A FDA reports in their estimated annual burden, we understand many/most are periodic reports of known and non-serious events. We suggest that focusing on receipt of new or unusual events, and not on reports for non-serious, well-characterized events, would be a more effective use of both Agency and industry time and effort. A possible mechanism for such change of focus could be to use the 3500A only for expedited cases and to allow reporting of known, non-serious events via line listings.
- (2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
 - We disagree with the estimates of one hour for completion of an average 3500A (from data collection to printing the report). Considering time involved in obtaining information from the customer, due diligence follow-up, computer entry and other aspects of case handling, including final regulatory processing, we believe that a more accurate estimate would be at least two hours of processing time per 3500A.

96N-0393

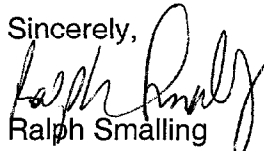
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(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

- We do not believe that patient safety is enhanced by continuing to gather the same amount of detail on known and well-characterized events as is collected for more unusual and/or serious events. This is particularly true if a report is medically unconfirmed (consumer-only report). Therefore, we would suggest that companies be required to collect minimal data for known and well-characterized cases, and to keep such data on hand, but not be required to provide individual case reports to the agency; summary data should be sufficient for tracking such known events. This would allow the company to focus on more intensive investigations of serious or unusual events, whether initially reported by consumers or health care professionals.

We thank you for the opportunity to comment on this subject.

Sincerely,

A handwritten signature in black ink, appearing to read "Ralph Smalling", with a long, sweeping horizontal line extending to the right.

Ralph Smalling

Vice President, Regulatory Affairs and Clinical Safety

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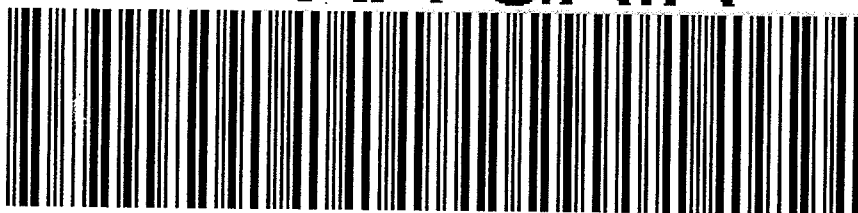
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